

### Remarks

This is in response to the non-final Office Action mailed June 27, 2007. Claims 10, 11, and 25 are canceled without prejudice or disclaimer. Claims 9, 15, 17, 22, and 23 are amended. Claims 1-9 and 12-24 remain pending. Reconsideration and allowance are requested for at least the following reasons.

#### I. Claim Rejections - 35 U.S.C. § 102

##### A. Hunn

Claims 1, 2, 4, 6, 9, 12, and 13 are rejected under 35 U.S.C. §102(e) as being anticipated by Hunn et al., U.S. Patent Publication No. 2004/0158207. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 1 is directed to a device for automatically retracting a needle used to introduce a cannula of a subcutaneous infusion device into a subcutaneous layer of skin of a patient. Claim 1 recites, in part, a trigger member including projections. Claim 1 further recites that, upon full introduction of the needle and associated cannula of the subcutaneous infusion device into a subcutaneous layer of skin of a patient, the projections release the needle hub, and the spring automatically moves the needle into the internal cavity of the housing into the retracted state while leaving the cannula of the subcutaneous infusion device in the subcutaneous layer of skin of the patient.

One example of a device configured as recited in claim 1 is shown in Figure 28A of the application. The example device shown in Figure 28A includes projections 444. As the housing 110, cylinder hub 120, and needle hub 130 are displaced in a direction A, barbs 335 of the needle hub 130 are forced inwardly by the projections 444 of the sleeve 140, and the barbs 335 are thereby uncoupled from engagement with the cylinder hub 120. Once the barbs 335 of the needle hub 130 are released from the cylinder hub 120, the spring 150, which has been compressed through the movement of the housing 110 in the direction A, propels the needle hub 130 and associated needle 336 in the direction B up through the cylinder hub 120 into the upper end 111 of the housing 110, as shown in Figures 29A and 29B. Application, p. 12, ll. 25.

Hunn fails to disclose or suggest a device configured in such a manner. Hunn discloses in Figures 9-12 a device that includes an inserting spring 21 that is triggered by the user pushing a first triggering button 24 to insert a needle carrier 27 including a needle 8 and a cannula 3.

Hunn also discloses a restoring spring 22 that is triggered by the user pushing a second triggering button 25 to remove the needle carrier 27 including the needle 8. Hunn, ¶ 0073. Hunn also discloses that the restoring spring 22 can be triggered automatically by operating a “trigger mechanism” or by simultaneously releasing a holding ring 23 when the user presses in buttons 6b to release the latch between latching projections 6c and the latching projections 1a of the body 1. Hunn, Fig. 9; ¶¶ 0077 and 0078.

However, Hunn fail to suggest a trigger member including projections that, upon full introduction of the needle and associated cannula of the subcutaneous infusion device into a subcutaneous layer of skin of a patient, release a needle hub, as recited by claim 1. Instead, Hunn only discloses a general concept of a “trigger mechanism” or releasing of a holding ring, but fails to disclose projections configured as recited by claim 1. Reconsideration and allowance of claim 1, as well as claims 2, 4, and 6 that depend therefrom, are therefore requested.

Claim 9 is directed to a device for inserting a subcutaneous infusion device into skin of a patient. Claim 9 recites, in part, a cap configured to be coupled to the housing, the cap including a tamper-evident band, wherein the tamper-evident band remains coupled to the housing when the cap is removed from the housing. The Action concedes that Hunn fails to disclose or suggest such a cap including a tamper-evident band. Reconsideration and allowance of claim 9, as well as claims 12 and 13 that depend therefrom, are therefore requested.

**B. Marano-Ford**

Claims 1, 3-10, 13, and 15-25 are rejected under 35 U.S.C. § 102(e) as being anticipated by Marano-Ford et al., U.S. Patent No. 6,926,694. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 1 recites a trigger member including projections. Claim 1 further recites that, upon full introduction of the needle and associated cannula of the subcutaneous infusion device into a subcutaneous layer of skin of a patient, the projections release the needle hub, and the spring automatically moves the needle into the internal cavity of the housing into the retracted state while leaving the cannula of the subcutaneous infusion device in the subcutaneous layer of skin of the patient.

Marano-Ford fails to disclose or suggest a trigger member, or a spring that automatically moves the needle into the internal cavity of the housing into the retracted state. In fact, Marano-

Ford only discloses springs (e.g., springs 222, 276) that are used to advance insertion sets. See, e.g., col. 9, ll. 53-55. Marano-Ford fails to disclose or suggest retraction. Reconsideration and allowance of claim 1, as well as claims 3-8 that depend therefrom, are requested.

Claim 9 recites a cap configured to be coupled to the housing, the cap including a tamper-evident band, wherein the tamper-evident band remains coupled to the housing when the cap is removed from the housing. The Action concedes that Marano-Ford fails to disclose a cap including a tamper-evident band. Reconsideration and allowance of claim 9, as well as claim 13 that depends therefrom, are therefore requested.

Claim 15 is directed to device for inserting a subcutaneous infusion device into skin of a patient. Claim 15 recites, in part, a cap coupled to the housing, the cap including a tamper-evident band, wherein the tamper-evident band remains coupled to the housing when the cap is removed from the housing. Claim 15 is therefore allowable over Marano-Ford. Reconsideration and allowance of claim 15, as well as claim 16 that depends therefrom, are requested.

Claim 17 is directed to a method for retracting a needle of a device used to introduce a cannula of a subcutaneous infusion device into a subcutaneous layer of skin of a patient. Claim 17 recites, in part, removing a cap from the device, the cap including a tamper-evident band, wherein the tamper-evident band remains coupled to the housing when the cap is removed from the housing. Claim 17 is therefore allowable over Marano-Ford. Reconsideration and allowance of claim 17, as well as claims 18-21 that depend therefrom, are requested.

Claim 22 is directed to a method for inserting a subcutaneous infusion device into skin of a patient. Claim 22 recites, in part, providing a tamper-evident band coupled to the cap by tabs, coupling the tamper-evident band to the housing, and uncoupling the cap from the housing so that the tabs are broken and the tamper-evident band remains coupled to the housing. Claim 22 is therefore allowable over Marano-Ford. Reconsideration and allowance of claim 22, as well as claims 23 and 24 that depend therefrom, are requested.

## II. Claim Rejections - 35 U.S.C. § 103

Claims 11 and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Marano-Ford. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 11 is incorporated into claim 9, and claim 25 is incorporated into claim 22.

The Action concedes that Marano-Ford fails to disclose or suggest a tamper-evident bands. The Action states that tamper-evident bands are well known. To the extent that official notice is taken that it is known to provide tamper-evident bands in devices and methods for inserting a subcutaneous infusion device into skin of a patient, it is respectfully suggested that such a fact is not capable of instant and unquestionable demonstration as being well-known. Consequently, it is respectfully suggested that official notice of this fact is improper, and it is requested that documentary evidence of the fact be provided in the next Action. MPEP 2144.03.

III. Allowable Subject Matter

Claim 14 is allowed. The Examiner's assistance in identifying allowable subject matter is appreciated.

IV. Conclusion

Favorable reconsideration in the form of a Notice of Allowance is requested. Please contact the undersigned attorney with any questions regarding this application. Please charge any additional fees or credit any overpayment associated with this or any other paper to Deposit Account No. 13-2725.

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